Humanitarian Device Exemption

Review of Humanitarian Use Devices

Nicole Wolanski, CAPT, USPHS
Premarket Approval Program
Office of Device Evaluation
Center for Devices and Radiological Health (CDRH), FDA

Overview

- Premarket Submissions
- HUDs
- HDEs
 - Criteria & Content
 - Approval
 - Key Points
 - Stats

Devices – Premarket Submissions

Submissions for marketing clearance/approval

- 510(k) substantial equivalence
- De Novo classification of low risk devices without predicates
- PMA reasonable assurance of safety and effectiveness
- HDE reasonable assurance of safety and probable benefit

HUDs

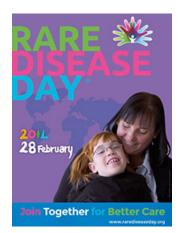
- Humanitarian Use Device (HUD)
 - For medical devices intended to treat or diagnose a disease or condition affecting fewer than 4,000 individuals in the US per year (21 CFR 814.(n))
 - HUD designation requests are reviewed by Office of Orphan Product Development
 - Additional information <u>www.fda.gov/orphan</u>

HUDs

- Nearly 7,000 rare diseases are known to affect roughly 30 million Americans.
 - approx 80% percent of rare diseases are genetic
 - about 1/2 of all rare diseases affect children
- Pediatric patients less than 22 years of age









HDEs – Criteria & Content

- Criteria
 - Received HUD designation from OOPD and
 - Device is not otherwise available
- Content
 - Device description
 - Non clinical data: engineering, software, biocompatibility, etc.
 - Clinical experience
 - Manufacturing
 - Physician and patient labeling

HDEs - Approval

- Approval Threshold
 - Does not pose unreasonable risk of illness or injury (i.e., <u>safety</u> is demonstrated), <u>AND</u>
 - Probable benefit outweighs the risk (i.e., exempt from effectiveness requirements of a PMA)
- Marketing Approval
 - IRB approval required before the HUD is used (except in emergency situations)
 - Labeling must clearly identify device as a HUD, and that effectiveness for that indication has not been demonstrated

Key Points

- Requirement to show safety and probable benefit
- HDE approval is marketing approval
- IRB approval required before device is used
- Annual reporting includes reassessment of qualification for HUD
- Draft guidance:
 - http://www.fda.gov/MedicalDevices/DeviceRegulationan
 dGuidance/GuidanceDocuments/ucm389154.htm?sourc
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HDE Stats

- 58 approved HDEs
- 8 devices approved under HDEs currently authorized to make a profit
- List of approved HDEs and their Summaries of Safety and Probable Benefit (SSPB) available at:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm

Contact Information

HUD Designation Information:

Office of Orphan Product Development Eric Chen - (301) 796-6327 <u>eric.chen@fda.hhs.gov</u>

HDE Information:

Nicole Wolanski – 301-796-6570 nicole.wolanski@fda.hhs.gov

PMA staff - 301-796 -5640

OIR - Runa Musib - 301-796-7014